K001866

DEC - 7 2000

510(k) Summary - TCM400 - Special 510(k)

Submitter:	Radiometer Medical A/S
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Contact Person	Kirsten Rønø

Trade Name	TCM400
Common name	Transcutaneous pO_2 monitoring system
Classification Name	Cutaneous Oxygen Monitor

Predicate Devices
RADIOMETER TCM3 with pO_2 sensor E5247 (P800043/S4) and RADIOMETER TCM1 (preamendment device).

Device Description
The TCM400 is a device that uses up to six non-invasive sensors placed on the patient's skin and that is intended to record transcutaneous oxygen partial pressures in adults not under gas anesthesia.

The TCM400 is a modification of the predicate TCM monitors.

The major new features are:
- the possibility of monitoring cutaneous oxygen tension on a patient with up to six sensors simultaneously
- the user interface with touch screen and enhanced data presentation capability
- the built-in barometer

The TCM400 has the same technological characteristics as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 7 2000

Ms. Kirsten Rono
Radiometer Medical A/S
Akandevej 21
DK-2700 Bronshoj
DENMARK

Re: K001866
Transcutaneous Oxygen Monitor, Model TCM 400
Regulatory Class: III (three)
Product Code: 73 LPP
Dated: November 8, 2000
Received: November 13, 2000

Dear Ms. Rono:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001866

510(k) Premarket Notification ~~K180066;~~ TCM400 Transcutaneous pO_2 Monitoring System

RADIOMETER COPENHAGEN

Response to the Reviewer's Questions of December 1, 2000 December 4, 2000

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~K180066~~ K001866
Device Name: *TCM400*
Indications for Use:

The TCM400 is a device that uses up to six non-invasive sensors placed on the patient's skin and that is intended to record transcutaneous oxygen partial pressures in adults not under gas anesthesia.

Division of Cardiovascular & Respiratory Devices
510(k) Number K001866

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)